



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-19-0666; Docket No. CDC-2019-0040]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS) .

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Healthcare Safety Network (NHSN). NHSN is a public health surveillance system that collects, analyzes, reports, and makes available data for monitoring, measuring, and responding to healthcare associated infections (HAIs), antimicrobial use and resistance, blood transfusion safety events, and the extent to which healthcare facilities

adhere to infection prevention practices and antimicrobial stewardship.

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019- by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton

Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including

- the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
  4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
  5. Assess information collection costs.

#### Proposed Project

National Healthcare Safety Network (NHSN) - Revision -  
National Center for Emerging and Zoonotic Infection  
Diseases (NCEZID), Centers for Disease Control and  
Prevention (CDC).

#### Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP),  
National Center for Emerging and Zoonotic Infectious  
Diseases (NCEZID), Centers for Disease Control and  
Prevention (CDC) collects data from healthcare facilities  
in the National Healthcare Safety Network (NHSN) under OMB  
Control Number 0920-0666. During the early stages of its

development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

NHSN currently has six components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), and the Dialysis Component. NHSN's new Neonatal Component is expected to launch during the summer of 2020. This component will focus on premature neonates and the healthcare-associated events that occur as a result of their prematurity. This component will be released with one module, which includes Late Onset-Sepsis and Meningitis. Late-onset sepsis (LOS) and Meningitis are common complications of extreme prematurity. Studies have indicated that 36% of extremely low gestational age (22-28 weeks) infants develop LOS and that 21% of very low birth weight infants surviving beyond 3 days of life will develop

LOS.<sup>1</sup> Meningitis occurs in 23% of bacteremic infants, but 38% of infants with a pathogen isolated from the cerebrospinal fluid may not have an organism isolated from blood. These infections are usually serious, causing a prolongation of hospital stay, increased cost, and risk of morbidity and mortality.

Some cases of LOS can be prevented through proper central line insertion and maintenance practices. These are addressed in the CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011*. However, almost one-third of LOS events in a quality-improvement study were not related to central-lines. Prevention strategies for the non-central line - related infection events have yet to be fully defined, but include adherence to hand-hygiene, parent and visitor education, and optimum nursery design features. Other areas that likely influence the development of LOS include early enteral nutritional support and skin care practices. The data for this module will be electronically submitted, and manual data entry will not be available. This will allow more hospital personnel to be available to care for patients and will reduce annual burden across healthcare facilities. Additionally, LOS data will be utilized for

prevention initiatives.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem. Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents. Under the Long-Term Care Facility Component, data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically

address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN. The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities. The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of March 2019, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to



NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities.

CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals,

inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily.

NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. This project has resulted in a significant increase in long-term care facilities reporting to NHSN. The collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m (d)), *(Attachment A)*.

The ICR previously approved in November of 2018 included revisions to 34 data collection forms and the addition of one new Patient Safety form for a total of 73 proposed data

collection forms. The proposed revisions to the information collection tools in NHSN include 38 changes to previously approved data collection tools. Incorporating all proposed revisions, the estimated burden for reporting reflects a decrease in hours by 2,472,007 hours for a total annual burden of 3,031,463 hours. Subsequently, the estimated cost burden reflects a decrease of \$86,726,153 for a total annual cost of \$110,756,566.

Estimated Annualized Burden Hours

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
57.100 NHSN Registration Form	2,000	1	5/60	167
57.101 Facility Contact Information	2,000	1	10/60	333
57.103 Patient Safety Component-- Annual Hospital Survey	5,175	1	75/60	6,469
57.105 Group Contact Information	1,000	1	5/60	83
57.106 Patient Safety Monthly Reporting Plan	6,000	12	15/60	18,000
57.108 Primary Bloodstream Infection (BSI)	5,775	5	38/60	18,288
57.111 Pneumonia (PNEU)	1,800	30	30/60	27,000
57.112 Ventilator-Associated Event	5,500	5	28/60	12,833
57.113 Pediatric Ventilator-Associated Event	334	120	30/60	20,040

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
(PedVAE)				
57.114 Urinary Tract Infection (UTI)	5,500	5	20/60	9,167
57.115 Custom Event	600	91	35/60	31,850
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	220	12	249/60	10,956
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	165	12	302/60	9,966
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	302/60	1,661,000
57.120 Surgical Site Infection (SSI)	4,500	11	35/60	28,875
57.121 Denominator for Procedure	4,500	680	10/60	510,000
57.122 HAI Progress Report State Health Department Survey	55	1	45/60	41
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	1,500	12	5/60	1,500
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification	2,000	12	5/60	2,000

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
Tables				
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	25/60	44,375
57.126 MDRO or CDI Infection Form	720	12	30/60	4,320
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60	39,875
57.128 Laboratory-identified MDRO or CDI Event	4,800	87	20/60	139,200
57.129 Adult Sepsis	50	250	25/60	5,208
57.137 Long-Term Care Facility Component - Annual Facility Survey	2,220	1	120/60	4,440
57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,150	24	15/60	12,900
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,200	12	20/60	8,800
57.140 Urinary Tract Infection (UTI) for LTCF	400	12	30/60	2,400
57.141 Monthly Reporting Plan for LTCF	2,220	12	5/60	2,220
57.142 Denominators for LTCF Locations	2,220	12	250/60	111,000
57.143 Prevention Process Measures Monthly Monitoring for LTCF	375	12	5/60	375
57.150 LTAC Annual		1	70/60	583

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
Survey	500			
57.151 Rehab Annual Survey	1,200	1	70/60	1,400
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60	400
57.203 Healthcare Personnel Safety Monthly Reporting Plan	-	1	5/60	-
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333
57.205 Exposure to Blood/Body Fluids	50	50	60/60	2,500
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375
57.207 Follow-Up Laboratory Testing	50	50	15/60	625
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	417
57.300 Hemovigilance Module Annual Survey	500	1	85/60	708
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	1/60	100
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	70/60	7,000
57.305 Hemovigilance	500	10	10/60	833

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
Incident				
57.306 Hemovigilance Module Annual Survey - Non-acute care facility	500	1	35/60	292
57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	20/60	667
57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	20/60	667
57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	20/60	167
57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	20/60	333
57.311 Hemovigilance Adverse Reaction - Febrile Non- hemolytic Transfusion Reaction	500	4	20/60	667
57.312 Hemovigilance Adverse Reaction - Hypotensive	500	1	20/60	167

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
Transfusion Reaction				
57.313 Hemovigilance Adverse Reaction - Infection	500	1	20/60	167
57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	20/60	167
57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	500	1	20/60	167
57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	20/60	167
57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	20/60	167
57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	500	2	20/60	333
57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	20/60	167
57.320 Hemovigilance	500	1	20/60	167



Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
Adverse Reaction - Other Transfusion Reaction				
57.400 Outpatient Procedure Component-Annual Facility Survey	700	1	10/60	117
57.401 Outpatient Procedure Component - Monthly Reporting Plan	700	12	15/60	2,100
57.402 Outpatient Procedure Component Same Day Outcome Measures	200	1	40/60	133
57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	200	400	40/60	53,333
57.404 Outpatient Procedure Component - SSI Denominator	700	100	40/60	46,667
57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	700	5	40/60	2,333
57.500 Outpatient Dialysis Center Practices Survey	7,100	1	127/60	15,028
57.501 Dialysis Monthly Reporting Plan	7,100	12	5/60	7,100
57.502 Dialysis Event	7,100	30	25/60	88,750
57.503 Denominator for Outpatient Dialysis	7,100	12	10/60	14,200
57.504 Prevention Process Measures	1,760	12	75/60	26,400

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour)	Total Burden (Hours)
Monthly Monitoring for Dialysis				
57.505 Dialysis Patient Influenza Vaccination	860	60	10/60	8,600
57.506 Dialysis Patient Influenza Vaccination Denominator	860	1	5/60	72
57.507 Home Dialysis Center Practices Survey	430	1	30/60	215
	Total Estimated Annual Burden (Hours)			3,031,463

**Jeffrey M. Zirger,**

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2019-11650 Filed: 6/4/2019 8:45 am; Publication Date: 6/5/2019]